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|--|-------------|----------------------|-------------------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
| 10/506,472   | 04/06/2005  | Jeremy Marshall      | 3003-1153                     | 8915             |
| 466 7590 04/16/2007<br>YOUNG & THOMPSON<br>745 SOUTH 23RD STREET<br>2ND FLOOR<br>ARLINGTON, VA 22202 |             |                      | EXAMINER<br>GILBERT, ANDREW M |                  |
|  |             |                      | ART UNIT                      | PAPER NUMBER     |
|  |             |                      | 3767                          |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE            | DELIVERY MODE                 |                  |
| 3 MONTHS   |             | 04/16/2007           | PAPER                         |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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|------------------------------|-------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/506,472 | Applicant(s)<br>MARSHALL ET AL. |  |
|                              | Examiner<br>Andrew M. Gilbert | Art Unit<br>3767                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed on 1/24/2007 and 12/21/2006.
2. In the reply, the Applicant amended claim 1 and submitted replacement sheet for Figure 1.
3. The submission of new Fig 1 has obviated the previous objection to the drawings.
4. Thus, claims 1-4, 7-8 are pending for examination.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recited the limitations "the second spring meanwhile serving to retain the syringe seated at its forward position." The Examiner is still unclear as to the recitation of this limitation in relation to the metes and bounds of claim 1. It appears that the Applicant is intending to recite that the second spring functions to retain the syringe seated at its forward position, or the extended position wherein the needle is penetrating the skin. However, as claimed in claim 1, the second spring acts in opposition to the first spring that applies the force necessary to move the needle into the extended position to pierce the skin and perform the injection. The force and function of the second spring, as claimed in claim 1, appears to be in opposition to

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retaining the syringe seated at its forward position. It appears to the Examiner, that the first spring acts to retain the syringe seated at its forward position as claimed in claim 1. Thus, the Examiner is unclear on how the second spring serves to retain the syringe seated at its forward position. The Examiner further notes that the function of the second spring in this manner becomes clearer upon introduction of the 3<sup>rd</sup> spring as claimed in the dependent claims 3-4 and 7-8. The Examiner recommends incorporating the limitations of the 3<sup>rd</sup> spring into the independent claim, or defining how the syringe is retained seated at its forward position in terms of the 1<sup>st</sup> and 2<sup>nd</sup> springs.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergens et al (6270479). Bergens et al discloses an injection device (Fig 1A-D) having a housing (Figs 1A-D) with a spring drive operable firstly to urge a syringe within the housing forwards to a forward position to project its needle from the forward end of the housing (Figs. 1A-D) and then to press a piston (125) within the syringe forwards to eject a dose through the needle (Figs 1A-D; col 11, lns 44-col 13, ln 19); wherein the spring drive includes a first spring (141) that acts between the housing and a plunger (126) aligned to cooperate with a piston (Figs 1A-D; col 11, lns 44-col 13, ln 19) to urge the plunger forwardly and a second spring (156) that acts in compression between the

plunger and the syringe in opposition to the first spring when the plunger presses said piston forwards to eject the dose (col 12, lns 29-33, 48-50; col 13, lns 2-6; wherein the Examiner notes that the plunger (126) ends proximally to the spring (156) as shown in Figs 1a), the second spring being weaker than the first spring but being sufficiently stiff to be in an expanded state when the syringe reaches its forward position with its needle penetrating the flesh of a patient (col 12, lns 29-33, 48-50; col 13, lns 2-6) whereupon the first spring, as it fully expands, will then compress the second spring to urge the plunger forwards and thereby move the piston and expel the dose within the syringe (Figs 1A-D; col 11, lns 44-col 13, ln 19), the second spring meanwhile serving to retain the syringe seated at its forward position (Figs 1A-D; col 11, lns 44-col 13, ln 19); wherein the plunger has a collar (153) slidable lengthwise within limits (Figs 1A-D; col 11, lns 44-col 13, ln 19), and the second spring bears on the rear side of this collar while the forward side of the collar co-operated with the syringe (Figs 1A-D; col 11, lns 44-col 13, ln 19); including a third, light spring (134) urging the syringe rearwardly so that its needle is retracted within the housing prior to use (Figs 1A-D; col 11, lns 44-col 13, ln 19); and the third spring encircles the syringe and acts between a rear flange of the syringe and an internal shoulder of the housing (Figs 1A-D; col 11, lns 44-col 13, ln 19).

### ***Response to Arguments***

9. Applicant's arguments filed 12/21/2006 have been fully considered but they are not persuasive.
10. The Applicant argues that Bergens et al the second spring (156) never acts on the drive plunger (142) at the same time as the drive spring (141) but before the drive

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plunger contacts with the syringe plunger (126), the spring (156), ceases acting on either plunger (Remarks, pg 8, paragraph 3-pg 9, paragraph 1).

11. In response to applicant's argument, the Examiner first notes that the Applicant has recited that the "a first spring that *acts between* the housing and a plunger" and "a second spring that *acts* in compression *between* the plunger and the syringe" (emphasis added). The recitation of acting between does not necessitate that the 1<sup>st</sup> or 2<sup>nd</sup> springs physically contact the housing, plunger, or syringe; rather, the 1<sup>st</sup> and 2<sup>nd</sup> springs need only to be disposed between the respective components. The Examiner recommends adding the limitations that the 1<sup>st</sup> and 2<sup>nd</sup> springs contact the respective elements (ie – the plunger, syringe and housing).

12. Secondly, the Examiner disagrees with the Applicant's characterization that the 2<sup>nd</sup> spring ceases acting on either the drive or syringe plunger. The Examiner finds no such basis for such a statement. Rather, Bergens et al discloses a 1<sup>st</sup> spring (141) that acts between the housing (100, Fig 1a) and the plunger (126, Fig 1a) and a 2<sup>nd</sup> spring (156) that acts between the proximal end of the syringe (124) in opposition to the 1<sup>st</sup> spring (col 12, lns 46-50, and col 13, lns 2-6; Fig 1a-d) when the plunger (126) presses said piston (125) forwards to eject the dose. As explicitly discloses, the 2<sup>nd</sup> spring is weaker than the 1<sup>st</sup> spring (col 12, lns 46-50) and is sufficient stiff to be in an expanded state when the syringe reaches its forward position with its needle penetrating the skin and being further compressed by the further expansion of the 1<sup>st</sup> spring to urge the plunger forwards and expel the dose (col 12, lns 58-col 12, lns 19). At no time does the

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2<sup>nd</sup> spring cease acting on either the drive or syringe plunger. The rejection is maintained.

***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

